bites,'' ''minor cuts,'' or ''minor scrapes'').

(c) *Warnings.* The labeling of the product contains the following warnings under the heading ''Warnings'':

(1) ''For external use only. Avoid contact with the eyes.''

(2) *For products containing aluminum acetate identified in § 347.10(a) or witch hazel identified in § 347.10(c).* ''If condition worsens or symptoms persist for more than 7 days, discontinue use of the product and consult a'' (select one of the following: ''physician'' or ''doctor'').

(3) *For products containing aluminum acetate identified in § 347.10(a) used as a compress or wet dressing.* ''Do not cover compress or wet dressing with plastic to prevent evaporation.''

(d) *Directions.* The labeling of the product contains the following information under the heading ''Directions'':

(1) *For products containing aluminum acetate identified in § 347.10(a)*—(i) *For products used as a soak.* ''For use as a soak: Soak affected area in the solution for 15 to 30 minutes. Discard solution after each use. Repeat 3 times a day.''

(ii) *For products used as a compress or wet dressing.* ''For use as a compress or wet dressing: saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Discard solution after each use. Repeat as often as necessary.''

(2) *For products containing aluminum sulfate identified in § 347.10(b) for use as a styptic pencil.* ''Moisten tip of pencil with water and apply to the affected area. Dry pencil after use.''

(3) *For products containing witch hazel identified in § 347.10(c).* ''Apply to the affected area as often as necessary.''

[58 FR 54462, Oct. 21, 1993, as amended at 59 FR 28768, June 3, 1994]

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

SOURCE: 57 FR 27656, June 19, 1992, unless otherwise noted.

Subpart A—General Provisions

§ 348.1 Scope.

(a) An over-the-counter external analgesic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 348.3 Definitions.

As used in this part:

(a) *Male genital desensitizing drug product.* A drug product applied to the penis to help in temporarily slowing the onset of ejaculation.

(b) [Reserved]

Subpart B—Active Ingredients

§ 348.10 Analgesic, anesthetic, and antipruritic active ingredients.

The active ingredient of the product consists of any of the following within the specified concentration established for each ingredient: